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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,922		Rodney E. Phillips	FHW-102US	1256

7590 04/20/2004

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EXAMINER	
DIBRINO, MARIANNE NMN	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,922	PHILLIPS ET AL.	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38 and 40-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *1-38 and 40-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 4/4/02 is acknowledged and has been entered. Restriction is required under 35 U.S.C. 121 and 372.

2. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-18 and 20, drawn to a method of screening for a cell comprising binding/internalizing a moiety to/into a cell

II. Claims 22-29, 31, 34 and 38, drawn to a moiety/composition thereof/kit comprising a moiety that binds to a receptor that recognizes an MHC/peptide complex and a second part comprising an agent that is internalized by a cell expressing the receptor after the first part binds to the said receptor

III. Claims 32 and 33, drawn to an apparatus and kit thereof for performing a method of binding/internalizing a moiety to/into a cell

IV. Claims 35-37, drawn to a method for treating a disorder using a moiety that binds to a receptor that recognizes an MHC/peptide complex and a second part comprising an agent that is internalized by a cell expressing the receptor after the first part binds to the said receptor

V. Claim 40, drawn to a kit containing an apparatus for performing a method of binding/internalizing a moiety to/into a cell and further comprising a moiety

VI. Claims 19, 41 and 44, drawn to a therapeutically active cell/composition thereof

VII. Claims 42 and 43, drawn to a method for treating a disorder or condition involving T cells using a therapeutically active cell

VIII. Claims 1, 7-10, 12-15, 17, 21 and 30, drawn to a method of treatment/therapy comprising binding/internalizing a moiety to/into a cell and killing it.

3. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Claim 1 of the instant application does not provide a technical feature that is distinguished over the prior art, as evidenced by DeBell et al (Cellular Immunology 127, 159-171, 1990). DeBell

et al teach a method of binding an anti-TCR mAb (i.e., a moiety that binds to a component of the TCR, a receptor on a cell that recognizes an MHC/peptide complex) to a cell at temperature of 37 degrees Centigrade (especially page 164 at the second paragraph).

Therefore, the instant invention lacks Unity of Invention.

4. If Applicant elects Group I, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method (a ***specific moiety AND a specific cell and specific method steps***, for example, MHC/peptide/diptheria toxin with specific modification(s) such as Lys516Ala and a T cell) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

5. If Applicant elects Group II, Applicant is further required to (1) elect a single disclosed species (a ***specific moiety***, for example, MHC/peptide/diptheria toxin with specific modification(s) such as Lys516Ala) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

6. If Applicant elects Group III, Applicant is further required to (1) elect a single disclosed species of component of the kit AND a specific apparatus (a ***specific moiety***, for example, MHC/peptide/diptheria toxin with specific modification(s) such as Lys516Ala and a single disclosed species of apparatus) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

7. If Applicant elects Group IV, Applicant is further required to (1) elect a single disclosed species of moiety and a specific disorder to be treated (a ***specific moiety that is internalized by a specific cell and a specific disorder to be treated***, for example, MHC/peptide/diptheria toxin with specific modification(s) such as Lys516Ala that binds to a T cell and treatment of an autoimmune disorder) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

8. If Applicant elects Group V, Applicant is further required to (1) elect a single disclosed species of component of the kit (a ***specific apparatus for performing a method of binding/internalizing a moiety AND the specific moiety***, for example, a single disclosed apparatus for performing a method of binding/internalizing MHC/peptide/diptheria toxin with specific modification(s) such as Lys516Ala and the internalizing MHC/peptide/diptheria toxin with specific modification(s) such as Lys516Ala moiety) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

9. If Applicant elects Group VI, Applicant is further required to (1) elect a single disclosed therapeutically active cell/composition thereof (*a specific therapeutically active cell that has bound or internalized a specific moiety*, for example, a T cell that has bound or internalized MHC/peptide/diptheria toxin with specific modification(s) such as Lys516Ala) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

10. If Applicant elects Group VII, Applicant is further required to (1) elect a single disclosed therapeutically active cell/composition thereof to be used and a specific disorder to be treated (*a specific therapeutically active cell that has bound or internalized a specific moiety*, for example, a T cell that has bound or internalized MHC/peptide/diptheria toxin with specific modification(s) such as Lys516Ala and treatment of a specific viral disorder) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

11. If Applicant elects Group VIII, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method (a ***specific moiety AND a specific cell and specific method steps***, for example, MHC/peptide/diptheria toxin with specific modification(s) such as Lys516Ala and a T cell) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

12. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

13. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

14. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

15. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

16. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

18. The examiner has required restriction between product and process claims. Where Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in

accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chan Y Christina, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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